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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,679	11/30/2001	Fumiaki Ikeda	216008US0PCT	1107
22850	7590	11/13/2003	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MOHAMED, ABDEL A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>		
	09/926,679		IKEDA ET AL.		
	<b>Examiner</b>		<b>Art Unit</b>		
Abdel A. Mohamed		1653			

**-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 28 February 2002.

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-9 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All   b) ☐ Some \*   c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> .	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____
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### **DETAILED ACTION**

#### **ACKNOWLEDGMENT FOR PRIORITY, IDS, STATUS OF THE APPLICATION AND CLAIMS**

1. This application is filed under 35 U.S.C. 371 on 11/30/01 having a filing date of 5/24/00 of PCT/JP00/03340. Acknowledgment is made of Applicant's claim for priority based on Australian Application No. PQ 0663 having a filing dates of 5/31/99. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The information disclosure statement (IDS) and Form PTO-1449 filed 2/28/02 are acknowledged, entered and considered. Claims 1-9 are present for examination.

#### **DISCLOSURE OBJECTED TO, MINOR INFORMALTIES**

2. The disclosure is objected because of the following informalities: On page 10, line 10, for incorporating U.S. Patent No. 5,569,946 to relate to the lipopeptide compound I. However, U.S. Patent No. 5,569,946 is related to stacked gate flash memory cell structure and process, which uses a large ion, implant beam to form the source and drain regions in the cell, and as such it is directed to different subject matter. Also, on page 11, last paragraph in the recitation "bronchus" twice. Thus, it is believed to be typographical errors. Appropriate correction is required.

#### **TITLE OF THE INENTION IS NOT DESCRIPTIVE**

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. See For Example "Combination use of pneumocandin antifungal drugs for treatment of fungal pathogens".

**STATEMENT OF STATUTORY BASIS, 35 U.S.C. 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

**CLAIMS REJECTION-35 U.S.C. § 112<sup>2nd</sup> PARAGRAPH**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 provides for the use of the lipopeptide compound I in the preparation of a medicament for simultaneous, separate or sequential use for the prevention and/or treatment of the infectious diseases caused by the fungal pathogen, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

merely recites a use without any active, positive steps delimiting how this use is actually practiced.

**CLAIMS REJECTION-35 U.S.C. 112<sup>1st</sup> PARAGRAPH.**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical formulations of cyclic lipopeptide compound I *in vitro* combination with amphotericin B (AMPH-B), itraconazole (ITCZ), Nikkomycin X, and flucytosine (5-FC) against *Aspergillus fumigatus* which were examined macroscopically for growth and compared to control (no drug). MIC was visually determined as the lowest concentration resulting in prominent decrease in turbidity compared to controls, does not reasonably provide enablement for a method of treatment or inhibition of the infectious diseases caused by the fungal pathogen (as listed in claim 6), by administering an effective amount of a lipoprotein compound I in combination with azoles, polyene, purine nucleotide inhibitor, pyrimidine nucleotide inhibitor, protein elongation factor inhibitor, bactericidal/permeability inducing protein product or polyoxin, and to a pharmaceutical formulations thereof for the prophylactic and/or therapeutic treatment of all kinds of the infectious diseases caused by the fungal pathogen as claimed in claim 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared *per* the factors indicated in the decision *In re Wands*, 8 USPQ2 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art;
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and
- 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and state of the prior art in the assessment of undue experimentation.

- 1) the nature of the invention;

The instantly claimed invention is directed to a method of treatment or inhibition of the infectious diseases caused by the fungal pathogen (as listed in claim 6), by administering an effective amount of a lipoprotein compound I in combination with azoles, polyene, purine nucleotide inhibitor, pyrimidine nucleotide inhibitor, protein elongation factor inhibitor, bactericidal/permeability inducing protein product or polyoxin and to a pharmaceutical formulation thereof.

- 2) the breadth of the claims;

The scope of the claims include a method for treatment or inhibition of the infectious diseases caused by all kinds of fungal pathogens comprising administering an

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effective amount of lipopeptide compound I in combination with azoles such as fluconaze, voriconze, itraconazole, miconazole, ER 30346, SCH 56592; polyenes such as amphotercin B, nystatin or liposomal and lipid forms thereof such as Abelcet, AmBisome and Amphocil; purine or pyrimidine nucleoside inhibitors such as flucytosine; or polyoxins such as nikkomycins or other chitin inhibitors, elongation factor inhibitors such as sordarin and analogs thereof, mannan inhibitors such as predamycin, bactericidal/permeability-inducing(BPI) protein products such as XMP.97 or XMP.127 or complex carbohydrate antifungal agents such as CAN-296 in combination with a pneumocandin derivatives, etc. pharmaceutical formulations thereof as claimed in claims 1-9. The specification does not disclose one reasonable method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims. The specification lacks guidance/direction as to how to employ a pharmaceutical preparation useful for treatment or inhibition of the infectious diseases caused by the fungal pathogen selected from the fungi recited in claim 6 by administering an effective amount of a lipopeptide compound I in combination with any or all of the drugs recited above in the manner claimed in claims 1-9.

Further, the first paragraph of 35 U.S.C. 112 requires, inter alia, that a patent specification provide sufficient guidance to enable a person skilled in the art to make and use the claimed invention without undue experimentation. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). While patent Applicants are not directed to disclose every species that falls within a generic claim, id. At 496, 20 USPQ2d at 1445, it is well settled that “the scope of the claims must bear a reasonable

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correlation to the scope of the enablement provided by the specification". In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

3) the predictability or unpredictability of the art;

As acknowledged by Applicant on pages 2-3 in the instant specification under Background Art, that the claimed lipopeptide compound I have shown potent *in vivo* activity against some opportunistic mycotic infections such as *Candida*, *Pneumocystis carinii* and *Aspergillus*; however, the present uses, i.e., polyenes, such as amphotericin B, cause severe side effects and azoles, such as fluconazole, are only fungistatic. Further, in view of the fact as stated in the instant specification on page 11, lines 31 to page 12, lines 4, that the fungi recited (claimed in claim 6) are well known to cause various infection disease in skin, hair, oral mucosal, gastrointestinal tract, bronchus, lung, endocardium, brain, meninges, urinary organ, vaginal portion, oral cavity, ophthalmus, systemic, kidney, heart, external auditory canal, bone, nasal cavity, paranasal cavity, spleen, liver, hypodermal tissue, lymph duct, gastrointestinal, articulation, muscle, tendon, interstitial plasma cell in lung, and so on. Furthermore, there is no drug interaction and efficacy studies conducted with the lipopeptide compound I in combination with the various drugs claimed to rule out the side effects acknowledged by Applicant. Thus, clearly showing the unpredictable nature of compounds in the method of treatment claimed.

4) the amount of direction or guidance presented;

The specification teaches pharmaceutical formulations of cyclic lipopeptide compound I *in vitro* combination with amphotericin B (AMPH-B), itraconazole (ITCZ), Nikkomycin X, and flucytosine (5-FC) against *Aspergillus fumigatus* which were



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examined macroscopically for growth and compared to control (no drug). MIC was visually determined as the lowest concentration resulting in prominent decrease in turbidity compared to controls as shown in Test Method on page 13 and Test Results of pages 14 and 15.

5) the presence or absence of working examples;

The instant specification does not teach for a method of treatment or inhibition of the infectious diseases caused by the fungal pathogen (as listed in claim 6), by administering an effective amount of a lipoprotein compound I in combination with azoles, polyene, purine nucleotide inhibitor, pyrimidine nucleotide inhibitor, protein elongation factor inhibitor, bactericidal/permeability inducing protein product or polyoxin, and to a pharmaceutical formulations thereof for the prophylactic and/or therapeutic treatment of the all kinds of the infectious diseases caused by the fungal pathogen as claimed in claim 8. Thus, Applicant's teachings do not adequately explain the evidence of making and using claimed lipopeptide compound I in combination with the various drugs recited in the claims for a method of treatment or inhibition of all kinds of infectious diseases caused by the various fungal pathogens because there are no working examples or data or evidences in the instant specification substantiating the above making and using the claimed lipopeptide compound I in combination with all kinds of antifungal agents for the method claimed in the instant invention; except for protocols.

6) the quantity of experimentation necessary;

The claimed invention is directed to a method of treatment or inhibition of the infectious diseases caused by the fungal pathogen (as listed in claim 6), by

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administering an effective amount of a lipoprotein compound I in combination with azoles, polyene, purine nucleotide inhibitor, pyrimidine nucleotide inhibitor, protein elongation factor inhibitor, bactericidal/permeability inducing protein product or polyoxin, and to a pharmaceutical formulations thereof for the prophylactic and/or therapeutic treatment of all kinds of the infectious diseases caused by the fungal pathogen as claimed in claim 8. Thus, in view of the broad diversity of fungal pathogens which encompass any kind of fungus of animals and humans, in view of the fact that animals and humans are out bread, in view of the fact that the antifungal agents have potentially adverse side effects as acknowledged on page 2 in the instant specification, in view of the fact that the instant invention lacks working example(s) for the claimed method, and in view of the recognized problems in the art that the claimed fungal pathogens are well known to cause the various infectious diseases recited on pages 11-12 in the instant specification; a reasonable doubt exist as to the enablement of the claimed method for treatment or inhibition of the infectious diseases caused by all kinds of fungal pathogens in all kinds of animals including humans by administering an effective amount of lipopeptide compound I in combination with the various antifungal agents in the manner claimed in claims 1-9. The claims are based on pure speculation that claimed method and pharmaceutical formulations thereof would be effective. Therefore, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled, since all kinds of pharmaceutical formulation comprising the various antifungal agents in combination with lipopeptide compound I in a method of treatment or inhibition of all kinds of diseases caused by fungal pathogens in an animal including human are contemplated and are encompassed as well as wide

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range of situations. The results desired appear to be highly dependent on all variables, the relationship of which is not clearly disclosed. Hence, one of ordinary skill in the art would not be able reproduce all the aspects the claimed invention pharmaceutical formulations as well as methods for treatment or inhibition of infectious diseases caused by all kinds of fungal pathogens, as encompassed in the claims would be effective and under what conditions.

7) the state of the prior art;

Thus, in view of the above and in view of the fact that the state of the prior art as admittedly acknowledged by Applicant on page 2 that the present uses, i.e., polyenes, such as amphotericin B, cause severe side effects and azoles, such as fluconazole, are only fungistatic. Hence, one of skill in the art would not accept the characterization of any and all therapeutic treatment protocols without working example(s) or data or evidence a believable on their face.

8) the relative skill of those skilled in the art;

Therefore, applying the Wands factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the extremely broad claims fro the reasons given above. Thus, in view of the quantity of experimentation necessary, the lack of adequate guidance or working examples or data, and the breadth of the claims; the claims are not commensurate in scope with the enabling disclosure. Hence, in consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teachings, and guidance presented. Therefore, absent of factual data to the contrary,

the amount and level of experimentation needed is undue. Accordingly, filing of evidence commensurate with the scope of the claims or amendment of the claims to what is supported by the enabling disclosure is suggested.

### **CLAIMS REJECTION-35 U.S.C. § 103(a)**

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/10782 taken with Franzot et al., (Antimicrobial Agents and Chemotherapy, Vol. 41, No. 2, pp. 331-336, February 1997) or Hector (U.S. Patent No. 5,030,619) or WO 96/11210.

The reference of WO 98/10782 is directed generally like the instantly claimed invention to antifungal combination therapy comprising the use of known antifungal agents such as the azoles or polyenes in combination with a pneumocandin derivative antifungal agent. Particularly, the reference teaches antifungal combination therapy comprising the use of azoles such as fluconazole, voriconazole, itraconazole, miconazole, ER 30346, SCH 56592; polyenes such as amphotericin B, nystatin or liposomal and lipid forms thereof such as Abelcet, AmBisome and Amphocil; purine or pyrimidine nucleotide inhibitors such as flucytosine; or polyoxins such as nikkomycins, in particular nikkomycin Z or other chitin inhibitors, elongation factor inhibitors such as sordarin and analogs thereof, mannan inhibitors such as predamycin, bacterial/permeability-inducing (BPI) protein products such as XMP.97 or XMP.127 or complex carbohydrate antifungal agents such as CAN-296 in combination with a pneumocandin derivatives (See e.g., abstract, pages 1 to pages 3, lines 1-20 and the claims) as directed to claims 1-9. Thus, the primary reference clearly discloses antifungal combination therapy using known antifungal agents such as the ones claimed in claims 1-9 with a pneumocandin derivative.

The claims differ by requiring a specific lipopeptide compound I as claimed in claim 1 in combination with the known antifungal agents such as azoles, polyenes and so forth for antifungal therapy. However, the primary reference of WO 98/10782 on page 5, lines 1-4, clearly suggests and/or contemplates that other pneumocandin derivatives than the ones used in the reference would be useful in combination therapy. Thus, clearly suggesting a synergistic antifungal combination by using the various pneumocandin derivatives for antifungal therapy. Further, the secondary reference of Franzot et al., describes pneumocandin L-743,872 enhancing the activities of amphotericin B and fluconazole against *C. neoformans* whereby a marked synergism was observed in all combinations of amphotericin B. Combinations with fluconazole

revealed activities including synergism and additivity but not antagonistic interactions (See e.g. abstract; page 33, col. 2, paragraph 2 to page 335, col. 2, paragraph 2). Furthermore, the reference of Hector teaches the use of synergistic fungicidal composition comprising a nikkomycin (such as nikkomycin X and Z) in combination with an echinocandin B known as cilofungin in treating fungal infection, especially against aspergillosis (See e.g., col. 1, lines 55 to col. 2, lines 10 and claims 1-9). Moreover, the reference of WO 96/11210 discloses the specific cyclic hexapeptides claimed in claim 1 (i.e., lipopeptide compound I) and their antifungal activities e.g., against *Candida* and *Cryptococcus* (See e.g. page 43, lines 1-33) and their inhibitory activity on 1,3- $\beta$ -D-glucan synthesis is referred on page 1, lines 16-34.

Therefore, as concluded on page 7 on the primary reference, given the above disclosure, it is thought that variations will occur to those skilled in the art. For example, it is thought that combination therapy using azoles other than fluconazole and pneumocandin derivative other than compound I may also be effective against fungal infections caused by the fungal pathogens. Furthermore, it is known that the pneumocandins, which are related to the echinocandins, inhibit cell wall 1,3- $\beta$ -D-glucan synthesis (See e.g., page 3, paragraph 1 of the primary reference). In the secondary reference of Franzot et al., it is suggested that the relative resistance of *C. neoformans* to pneumocandins resulted from absence of 1,3- $\beta$ -glucans in the cell wall of this yeast among other things. Hence, it is obvious that any inhibitor of 1,3- $\beta$ -D-glucan synthesis will act antifunagally if this 1,3- $\beta$ -D-glucan is part of the cell wall of the yeast.

Although, the specific combination of lipopeptide I as claimed in claim 1 with antifungal agents such as azoles, polyenes and so forth for antifungal therapy is not taught by the prior art of record; however, the reference of Franzot et al., teaches the synergistic effect of pneumocandin L-743,872 in combination with amphotercin B and fluconazole resulted in enhancing antifungal activity against *C. neoformans in vitro* as

measured by turbidity, quantitative CFU, and XTT reduction assays. Similarly, the reference of Hector teaches the synergistic effect of echinocandin B (cilofungin) in combination with nikkomycin to treat fungal infection such as aspergillosis. The primary reference of WO 98/10782 as discussed above teaches the antifungal combination therapy using various antifungal agents with a pneumocandin derivative and contemplates and/or suggests by stating that other pneumocandin derivatives than the ones used by the reference would be useful in the combination therapy. Thus, in view of this and in view of the known synergistic effects of pneumocandins in combination with antifungal agents as taught by Franzot et al. or Hector, one of ordinary skill in the art would have been motivated to test the various pneumocandin derivatives in combination with antifungal agents to obtain the known and recognized advantages of synergism thereof. Further, the reference of WO 96/11210 as discussed above discloses lipopeptide compound I of claim 1 having antifungal activity against *Candida* and *Cryptococcus* and inhibitory activity on 1,3- $\beta$ -D-glucan synthase. Thus, given the combined teachings of the prior art and since the synergistical action of lipopeptides such as the ones in the primary reference of WO 98/10782, and secondary references of Franzot et al. or Hector with the antifungal agents cited in claim 1 of the present invention are known and other lipopeptides are contemplated as acting in the same manner, one of ordinary skill in the art would be prompted to use the lipopeptides (i.e., lipopeptide compound I of claim 1) from the reference of WO 96/11210 in combination with other antifungal agents for the intended purposes of treating or inhibiting infectious diseases caused by fungal pathogens. Thus, the combined teachings of the prior art makes obvious the claimed invention for the reasons discussed above, absent of objective factual evidence or unexpected results to the contrary.

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### CONCLUSION AND FUTURE CORRESPONDENCE

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-1923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 Mohamed/AAM

November 7, 2003

  
CHRISTOPHER S. F. LOW  
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